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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/566,752	02/01/2006	James B. Jaquith	126-PCT2-US	5932
49580 7590 09/07/2007 PHILIP SWAIN, PHD C/O GOWLING LAFLEUR HENDERSON 1 PLACE VILLE MARIE, 37TH FLOOR			EXAMINER	
			HAVLIN, ROBERT H	
			ART UNIT	PAPER NUMBER
MONTREAL, CANADA			1626	
CHAIDH			MAIL DATE	DELIVERY MODE
			09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary    Examiner			Application No.	Applicant(s)			
Robert Havlin  The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CPR 1.136(a). In no event, however, may a reply be timely filed and the correspondence address of 37 CPR 1.136(b). In no event, however, may a reply be timely filed and the correspondence and the cor	Office Action Summary		10/566,752	JAQUITH ET AL.			
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WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of this may be available under the provisions of 37 CPR 1.13(8). In no event, may a high be limely filed after SIX (8) MONTHS from the mailing date of this communication.  If NO period for raph' is specified above, the maximum shalldery period under apply and vill expire SIX (8) MONTHS from the mailing date of this communication.  Any reply received by the Officia star than three medits after the mailing date of this communication, even if limely filed, may reduce any seared patient larm adjustment. See 37 CPR 1.704(b).  Status  1) ☑ Responsive to communication(s) filed on 27 June 2007.  2a) ☐ This action is FINAL.  2b) ☑ This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) ☑ Claim(s) 31-63 is/are pending in the application.  4a) Of the above claim(s) 37.41.47 and 53-63 is/are withdrawn from consideration.  5) ☐ Claim(s) 31-36 38-40.42-46 and 48-52 is/are rejected.  7) ☐ Claim(s) 31-36 38-40.42-46 and 48-52 is/are rejected.  7) ☐ Claim(s) ☐ is/are allowed.  6) ☑ Claim(s) ☐ is/are allowed.  6) ☐ Claim(s) ☐ is/are above to restriction and/or election requirement.  Application Papers  9) ☐ The specification is objected to by the Examiner.  10) ☐ The drawing(s) filed on ☐ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  Application Papers  9) ☐ The specification is objected to by the Examiner.  10) ☐ The drawing(s) filed on ☐ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  Application Papers  9) ☐ All b) ☐ Some * c) ☑ None of:  1. ☐ Certified copies of the priority documents have been received in Application No. ☐ .  2. ☐ Certified copies of the priority documents have been received in Application No. ☐ .  3. ☐ Copies of the certified copies of the priority documents have been received in Application No. ☐ .  3			ears on the cover sheet with the o	correspondence address			
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3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application	1) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	ate			

Art Unit: 1626

### **DETAILED ACTION**

Status of the claims: Claims 31-63 are currently pending. Claims 1-30 were cancelled and 31-63 were newly presented.

**Priority:** This application is a 371 of PCT/CA04/01484 (08/11/2004). The certified copy of the priority document is not part of the application file, therefore the priority date will be considered to be the actual US filing date (02/01/2006) of the application until conditions for claiming priority as described in the MPEP and PCT rule 17.1 are met. **IDS:** The IDS dated 2/1/2006 and 2/20/2007 have been considered.

#### Election/Restriction

1. Applicant's election with traverse of group I in the reply filed on 6/27/2007 is acknowledged. The traversal is on the ground(s) that restriction practice is not proper for a 371 application. This is not found persuasive because as explained in the requirement for restriction, the technical feature linking the claims is not novel, therefore the application lacks a special technical feature and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

The following claims are hereby withdrawn 37, 41, 47, and 53-63.

## Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 31-36, 38-40, 43-46, 48-49, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (US 5,057,614).

Art Unit: 1626

The applicant's invention reads on the following species: 3-(1-indolyt)-4-(1-methyl-3-indolyt)-1H-pyrrote-2,5-dione

Davis et al. (US 5,057,614) on column 23, example 46 teaches the same compound, in addition the reference also teaches pharmaceutical compositions thereof in claim 11, for example.

# **Double Patenting**

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 7,129,250. Although the conflicting claims are not identical, they are not patentably distinct from each other

Art Unit: 1626

because the claim recites 32 species, one of which has the same formula (but a simple positional isomer of a methyl group) as that claimed in this application, therefore it would have been immediately obvious to one of ordinary skill in the art to select the isomer of the instantly claimed invention from such few members. Furthermore, one of ordinary skill would be motivated to make the modifications described above with reasonable expectation for the same activity. Position isomers, and homologs, are generally of sufficiently close structural similarity that there is a presumed expectation that such compound possess similar properties. MPEP §2144.09, *Ex parte Henkel* 130 USPQ 474, (1-phenyl-3-methyl-4-hydroxypyrazole obvious over reference teaching 3-phenyl-5-methyl-4-hydroxypyrazole). *Ex parte Weston*, 121 USPQ 429. Thus, the instant claims are prima facie obvious over the claims in the '250 patent.

4. Claim 51 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,129,250. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim recites 10 species, one of which is identical to that claimed in this application, therefore it would have been immediately obvious to one of ordinary skill in the art to select the instantly claimed invention from such few members.

# Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 31-36, 38-40, 42-46, and 48-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Throughout the specification, and in the examples given to support the claims there is improper IUPAC nomenclature used such that it would create ambiguity as to what the applicant actually possessed. For example, the following elected species does not result in an

Example 167: 3-(3-(amidinothio)propyl)indol-1-yl)-4-(1-methylindol-3-yl)-4-pyrrole-2,5-dione

unambiguous definition of a chemical structure:

The applicant must verify that all chemical names are in accordance with the art accepted naming rules as laid out by the IUPAC. To further clarify what the applicant possessed chemical structure drawings would be appropriate.

#### Conclusion

All claims are rejected.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin Examiner

RH

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER